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WESTERN DISTRICT OF WASHINGTON
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UNITED STATES DISTRICT COURT, WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNDER SEAL,

Plaintiff,

No. 07-0248 BHS

vs.

UNDER SEAL

UNDER SEAL,

NOTE ON MOTION CALENDAR FOR:
APRIL 7, 2010

Defendants.

FILE UNDER SEAL

UNDER SEAL - 1
Case No. C07-0248



07-CV-00248-M

Honorable Benjamin H. Settle

UNITED STATES DISTRICT COURT, WESTERN DISTRICT OF WASHINGTON
AT TACOMA

UNITED STATES OF AMERICA, *ex rel.*
Marshall S. Horwitz, M.D.,

Plaintiff,

vs.

AMGEN INC. and DAVID C. DALE, et al.,

Defendants.

No. 07-0248 BHS

PLAINTIFF AND RELATOR'S *EX*
PARTE MOTION TO UNSEAL
COMPLAINT FOR LIMITED PURPOSES

NOTE ON MOTION CALENDAR FOR:
APRIL 7, 2010

FILE UNDER SEAL

I. INTRODUCTION

Plaintiff and relator Marshall S. Horwitz, M.D., Ph.D., asks respectfully that the seal in this *qui tam* matter be lifted partially, so that he and his counsel may discuss the allegations of this case with, and show a copy of the complaint¹ to, appropriate representatives of his employer. Allowing Dr. Horwitz to show the complaint to his employer will help enable him to assist as needed in the government's investigation of the allegations raised by that complaint. Thus, Dr. Horwitz's request comports with the purposes underlying the seal provision of the False Claims Act. For this reason, the government agrees with the relief requested by Dr. Horwitz. There being good justification for partially lifting the seal, Dr. Horwitz urges the Court to grant this motion.

¹ By "complaint," Dr. Horwitz means the amended complaint presently on file, but also the initial complaint he filed.

II. STATEMENT OF FACTS

On February 15, 2007, Dr. Horwitz filed the above-captioned matter with this Court. Per 31 U.S.C. § 3730(b)(2), which provides that the complaint in a *qui tam* action “shall be filed *in camera*, shall remain under seal for at least sixty (60) days, and shall not be served on the defendant until the court so orders,” Dr. Horwitz filed his complaint under seal. Later, Dr. Horwitz filed an amended complaint (hereafter, “complaint”). It, too, was filed under seal, and, as a result of government-requested extensions, it remains under seal to this day. The seal has, however, been lifted partially on two previous occasions: first, in order to enable the government to reveal the complaint to certain other relators and their counsel in other jurisdictions, and second, in order to enable the government to reveal the complaint to the defendants.

Dr. Horwitz’s complaint alleges manipulation of science and unlawful marketing practices on the part of the defendants, including the pharmaceutical company Amgen Inc. (“Amgen”). (*See generally Complaint; First Amended Complaint.*) Amgen manufactures two of the drugs at issue in this case, Aranesp and Neulasta. Aranesp is a red-blood-cell booster used to treat anemia, and one for which the federal government through Medicare and other programs has expended billions of dollars.

The government is in the midst of an investigation of matters raised by Dr. Horwitz’s complaint. (Declaration of Robert F. Lopez in Support of Motion To Unseal Complaint for Limited Purposes (“Lopez Decl.”), ¶ 2.) Toward the completion of its investigation, the government, as indicated above, has sought and received extensions of the time period within which the complaint is to remain sealed.

Amgen has produced a large volume of documents to the government in the course of the investigation. Given the volume of documents, the government has advised that it has had to move a good amount of them off-site. (Lopez Decl., ¶ 3) Accessing the documents remotely using the Department of Justice’s computer system requires a security clearance. (*Id.*) Dr.

1 Horwitz must undergo a background check so that he can be available to help review some of
2 these off-site documents. (*Id.*)

3 As part of his background check, federal agents will be contacting his employer, the
4 University of Washington. (Lopez Decl., ¶ 4.) Those contacted will want to know the reason for
5 the contact, and Dr. Horwitz would like to be able to advise them that the contact is in
6 connection with this suit. (*Id.*)

7 In addition, Dr. Horwitz and his counsel would like to be able to discuss Dr. Horwitz's
8 role in this suit with Dr. Horwitz's employer. (Lopez Decl., ¶ 5.) It would be helpful for Dr.
9 Horwitz and his counsel to have the ability as needed to share with appropriate University
10 officials Dr. Horwitz's complaint and to discuss the allegations he has made in that complaint.
11 (*Id.*)

12 Dr. Horwitz and his counsel have discussed the matters raised in this motion with the
13 Assistant United States Attorneys leading the referenced investigation who have agreed that
14 granting the relief requested in this motion will facilitate the government's investigation and
15 otherwise is in the interests of justice. (Lopez Decl., ¶ 6.)

16 III. LAW AND ARGUMENT

17 Dr. Horwitz, with the government's agreement, asks that the seal be lifted partially on the
18 complaint in this matter so that he may discuss its allegations with, and show a copy to, his
19 employer. Lifting the seal for this purpose would violate neither the letter nor spirit of the law
20 providing that a *qui tam* complaint remain under seal while the government's investigation is
21 ongoing. Rather, partially lifting the seal as requested would help to facilitate the government's
22 investigation.

23 31 U.S.C. § 3730(b)(2) provides that the complaint in a *qui tam* action "shall be filed *in*
24 *camera*, shall remain under seal for at least sixty (60) days, and shall not be served on the
25 defendant until the court so orders." The complaint has remained under seal while the
26

1 government continues its investigation. 31 U.S.C. § 3730(b)(3) (providing for extensions of the
2 seal).

3 As the government noted in its June 2009 motion to lift the seal partially in order to
4 reveal the complaint to Amgen, the purpose of the seal is “to advance Government
5 investigations.” (July 2000 Gov. Mot. at 3.) It added:

6 The Justice Department urged Congress to enact the seal provisions, and in doing
7 so, the Senate stated that:

8 Keeping the *qui tam* complaint under seal . . . is intended to allow
9 the Government an adequate opportunity to fully evaluate the
10 private enforcement suit and determine both if that suit involves
11 matters the Government is already investigating and whether it is
12 in the Government’s interest to intervene and take over the civil
13 action.

14 S. Rep. No. 99-345, 99th Cong., 2d Sess. 24, *reprinted in* 1986 U.S. Code Cong.
15 & Admin. News 5266, 5289.

16 (*Id.*²)

17 This policy that the Court examined in granting the government’s June 2009 motion also
18 would be served if the instant motion were granted. Permitting Dr. Horwitz and his counsel to

19 ² See also *United States ex rel. Lujan v. Hughes Aircraft Co.*, 67 F.3d 242 (9th Cir. 1995). As
20 the Ninth Circuit wrote:

21 By providing for the seal provision, Congress intended to strike a balance
22 between “the purposes of *qui tam* actions [and] . . . law enforcement needs[.]” S.
23 Rep. No. 345, 99th Cong., 2d Sess. 16, *reprinted in* 1986 U.S.C.C.A.N. 5266,
24 5289. The purpose of *qui tam* actions is to encourage more private false claims
25 litigation. See *id.*, *reprinted in* 1986 U.S.C.C.A.N. at 5288. The other side of the
26 balance recognizes the need to allow the Government an adequate opportunity to
fully evaluate the private enforcement suit and determine both if that suit involves
matters the Government is already investigating and whether it is in the
Government’s interest to intervene and take over the civil action. *Id.*, *reprinted in*
1986 U.S.C.C.A.N. at 5289. The seal provision provides an appropriate balance
between these two purposes by allowing the *qui tam* relator to start the judicial
wheels in motion and protect his litigative rights, while allowing the government
the opportunity to study and evaluate the relator’s information for possible
intervention in the *qui tam* action or in relation to an overlapping criminal
investigation. *Id.*

Id. at 245.

1 discuss the allegations of his complaint with, and to show a copy of that complaint to,
2 appropriate employer representatives will enable his employer to understand why Dr. Horwitz is
3 undergoing a background check and what his role is in this case. This understanding, in turn,
4 will help to facilitate Dr. Horwitz's availability to assist in the government's investigation as
5 needed. The government agrees with and supports this request for relief.

6 **IV. CONCLUSION**

7 Good cause exists to grant Dr. Horwitz's *ex parte* motion for partial unsealing of the
8 complaint he has filed in this matter, and Dr. Horwitz asks respectfully that his motion be
9 granted. A proposed form of order is submitted herewith.

10 Dated: April 7, 2010.

11 Respectfully submitted,

12 HAGENS BERMAN SOBOL SHAPIRO LLP

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